

### **REMARKS**

Claims 1-29, and 38 are pending in the subject application. Claims 1 and 38 have been amended to clarify the present invention's use of compounds being inhibitors of PDE2 that do not substantially inhibit COX I or II. Claim 7 has been amended to correct an obvious typographical error.

Claims 1 and 38 have been amended to more clearly state that the inhibitor should have an  $IC_{50}$  for PDE2 that is at least twice its  $IC_{50}$  for COX I or COX II. Support can be found in the specification at, for example, page 12, third full paragraph. Thus, the changes are not new matter.

Claim 7 has been amended to correct the spelling of "quinolinyll", which can be found in the recited list of possible "Y" species in independent claim 6 from which claim 7 depends. Thus, the change is not new matter.

Claims 30-37 and 39 have been canceled without prejudice to applicants' right to pursue the subject matter in this or any related patent application.

#### **Rejections under 35 U.S.C. §112, second paragraph**

The Examiner has rejected claims 1-5 and 38 for the term "substantial". Applicants respectfully submit that the claims have been amended to more clearly state the claimed invention by stating that the inhibitor should have an  $IC_{50}$  for PDE2 that is at least twice its  $IC_{50}$  for COX I or COX II. Applicants respectfully submit that the claims are now clear and definite and request withdrawal of the rejections.

#### **Rejections under 35 U.S.C. §103**

Claims 1-29 and 38 were rejected as allegedly unpatentably obvious over U.S. Patent No. 6,066,634 ("Sperl") in view of Berkow et al. (*Merck Manual of Medical Information*, Home Ed., 1997, p. 253).

Applicants respectfully submit that, while Sperl recites that the compounds can be used for autoimmune diseases, there is no specific recitation of lupus erythematosus. Berkow merely teaches that lupus erythematosus is an autoimmune disease. Applicants respectfully submit that the Examiner is impermissibly using an obvious to try standard to reach a determination of obviousness. The Examiner acknowledges that there are differences in pathologies among the various autoimmune diseases. All autoimmune diseases are not alike. Thus, lupus erythematosus is a species of the genus of

autoimmune diseases. There is no showing of specific efficacy to lupus erythematosus in Sperl. Thus, the present application is allowable and not obvious – similar to the allowability of chemical species selection patents – because while one in the art might be inspired to try the compounds in lupus erythematosus, there is no teaching that every autoimmune disease (such as lupus erythematosus) would be successfully treated.

Applicants respectfully suggest that the Examiner is impermissibly utilizing an obvious to try standard or is impermissibly utilizing hindsight, with the claims of the present invention as a template, to support the rejection. Accordingly, Applicants respectfully request withdrawal of the rejection.

### **Conclusion**

Applicants respectfully submit that the rejections have been overcome, the claims are in condition for Allowance, and request a timely Notice of Allowance be issued in this case. Commissioner is authorized to charge any deficiencies and credit any overpayment to OSI Pharmaceuticals, Inc. Deposit Account No. 502783.

Attorney for Applicants can be reached at the telephone number and address below.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date appearing below.

**OSI PHARMACEUTICALS, Inc.**  
By Shu M. Lee Date 05 Jan 2004

January 5, 2004  
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Respectfully submitted,



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